# 1AP20 Rec'd PCT/PTO 24 MAR 2006

# METHOD AND DEVICE FOR PILL DISPENSING

This application claims the benefit of U.S. Provisional Patent Application Serial No. 60/509,319, filed October 7, 2003, herein incorporated by reference.

#### Technical Field

5

10

15

The present invention relates generally to pill containers and, in particular, to a method and device for pill dispensing. In particular, it relates to a pill dispenser that dispenses pills no faster than a prescribed rate. Even more particularly, it relates to a pill dispenser that detects tampering and includes provisions for neutralization of the dispenser contents upon such detection.

# Copyrighted Materials

A portion of the disclosure of this patent document contains materials to which a claim of copyright protection is made. The copyright owner has no objection to the reproduction by anyone of the patent document or the patent disclosure as it appears in the U.S. Patent and Trademark Office patent files or records, but reserves all other rights with respect to the copyrighted work.

# Background of the Invention

In the past few years, the abuse of prescription oral narcotics has grown at an alarming rate. These narcotics are often addictive and abused by

2

patients who may take the medication more frequently than their prescribed rate. Such abuse can lead to severe medical problems for the abuser and can result in death, due to overdosing or extended exposure to the narcotics. Programs designed to treat and prevent such abuse costs society millions of dollars annually. For these reason, physicians are often reluctant to prescribe narcotics to individuals who may need them.

While many types of pill dispensers are known in the art, none limit pill dispensing to a prescribed rate, while reducing the chance for patient abuse of the prescribed medication. Therefore, the need exists for a dispenser that dispenses pills no faster than a prescribed rate and detects tampering with the dispenser. The need also exists for a dispenser that, in the event of user tampering, renders the pills impotent thereby reducing the chance of abuse by the patient. Additional aspects, advantages and other novel features of the invention will be set forth in part in the description that follows and in part will become apparent to those skilled in the art upon examination of the foregoing or may be learned with the practice of the invention.

### Summary of the Invention

5

10

15

20

25

In accordance with the purposes of the present invention as described herein, a new and improved pill dispensing device is described. The present invention includes a pill dispenser comprised of a container enclosing a holder, such as a chute, a gate, a sensor, and a neutralizing device.

In one embodiment, the chute contains a plurality of pills for release at a prescribed rate. The gate is positioned in communication with an opening of the chute and movement of the gate from an engaged position to an non-engaged position permits release of a pill from an opening of the chute. The dispensing device also may include a controller.

5

10

15

20

25

The controller includes at least one programmable microcontroller. The microcontroller is in communication with a timer, the sensor, and the neutralizing device. Additionally, the microcontroller activates an actuator that functions as a lock and repositions the gate. At a predetermined interval, the microcontroller repositions the gate for release of a pill from the chute.

The sensor, such as a conductive loop, detects tampering with the dispensing device. Upon detection of tampering, the sensor sends a signal to the controller and the controller activates a neutralizing device, thereby rendering the contents of the dispenser impotent.

In the following description there is shown and described one possible embodiment of this invention, simply by way of illustration of one of the modes best suited to carry out the invention. As it will be realized, the invention is capable of other different embodiments, and its several details are capable of modification in various, obvious aspects all without departing from the invention. Accordingly, the drawings and descriptions will be regarded as illustrative in nature and not as restrictive.

# Brief Description of the Drawings

The accompanying drawings incorporated in and forming a part of the specification, illustrate several aspects of the present invention, and together with the description serve to explain certain principles of the invention. In the drawings:

Figure 1a is a side view of the dispenser forming one possible embodiment of the present invention;

Figure 1b is a rear view of the dispenser of Figure 1;

WO 2005/041137 PCT/US2004/017228,

4

Figure 1c is an opposing side view of the side shown in Figure 1;

Figure 1d is a top view of the dispenser of Figure 1;

Figure 2 is an exploded view of the dispenser of Figure 1;

Figure 3 is a flowchart showing general use and operation of the dispenser of Figure 1;

Figure 4 is a detailed view of the gate and solenoid of Figure 2, illustrating the engaged and non-engaged positions;

Figure 5 is a block diagram of one possible embodiment of the controller of the present invention;

Figures 6a and 6b are diagrams illustrating various algorithms for detecting pill release from the dispenser;

Figure 7a is schematic of one possible embodiment of the conductive loop sensor of the present invention;

Figure 7b is a diagram showing the conductive loop sensor positioned on the dispenser of Figure 1;

Figure 8 is a diagram showing one possible embodiment of the pressure sensitive switch positioned on the dispenser of Figure 1;

Figure 9 is schematic of one possible embodiment of the capacitive sensor of the present invention;

Figure 10 is diagram showing one possible embodiment of the pressure sensor of the present invention.

## Detailed Description of the Invention

5

15

20

25

Reference is now made to Figures 1a-d and 2 illustrating one embodiment of the pill dispenser 10 of the present invention. In this document, all references to pill(s) relate broadly to all solid, liquid, and gases.

5

Additionally, pills may relate to prescription medication, non-prescription medication, or other. As illustrated, the pill dispenser 10 includes a container 12 having a holder, such as a chute 14, a gate 16, a controller 18, a sensor 20, and a neutralizing device 22.

The interaction between these elements regulates the release of

5

10

15

20

25

(step 106).

pills from the dispenser 10. Figure 3 shows a general overview of use and operation of the dispenser 10. In use, a doctor or other authorized individual determines the rate of pill release (step 100). Next, the pill dispenser 10 is programmed to release pills at this programmed rate (step 101). The dispenser is then loaded with the pills (step 102). After loading, the dispenser is sealed to prevent access to the contents of the dispenser 10 (step 103). The dispenser will then release pills at the programmed rate (step 104). It will continue to release pills at the programmed rate unless it detects tampering with the container (step 105). A sensor 20 detects tampering, such as attempts by an individual to access the contents of the container. If tampering is detected, the sensor 20 detects such activity, sends a signal to the controller 18 and the

The container 12 includes at least one outlet 24, such as an aperture, adapted for dispensing the contents, such as pills (not shown), stored in the container. In one embodiment, the container 12 may include a first and second cover 26a, 26b designed to seal the contents of the container 12. In this arrangement, the first and second covers 26a, 26b may attach to the container 12 in a manner to prevent or mitigate a user from tampering with the contents of the container 12. Thus, the covers 26a, 26b may attach to the container via high strength epoxy, glues, adhesives, welding, soldering, brazing, or otherwise. In addition to the substantially rectangular container 12

controller 18 activates a neutralizing device 22, thereby neutralizing the pills

WO 2005/041137 PCT/US2004/017228.

6

shown in Figure 1, the container may have a substantially cylindrical shape or any other shape, dimensions, or configuration, and be formed from any material. Preferably, the container would be portable and consist of a material, such as stainless steel, polymer/fiber composites, ceramic lined metals, or other materials having the strength and other material properties to withstand neutralization of the container 12 contents (as discussed below in further detail).

5.

10

15

20

25

With reference to Figure 2, the chute 14 comprises a tube having a first and second opening 14a, 14b and an internal opening slightly greater than the dimensions of the pills it will retain, so as to provide the necessary clearance to allow pill passage. As shown, the chute 14 may have a substantially helical shape. Alternatively, the chute 14 may be an elongated tube, or be of any suitable shape or size configuration. A gate 16 is positioned in communication with one of the openings 14a, 14b. In one embodiment, the gate includes a body having an arcuate surface 16a. The gate 16 is adapted to substantially cover the outlet 24 of the container 12.

An actuator that functions like a lock, such as a solenoid 17 in communication and activated by the controller 18, repositions the gate 16 from an engaged position A to a non-engaged position B, as shown in Figure 4a. This repositioning permits the release of a pill from an opening of the chute 14. In one embodiment, the dispenser 10 may include a dispensing member 28 having an aperture 30 adapted to receive the pill from the chute 14. In this configuration, the repositioning of the gate 16 permits the movement of the dispensing member 28 and the actual dispensing of a pill. As shown in Figures 1 and 2, the container 12 may also include a button 32 linked to the dispensing member 28. When the gate 16 is in the non-engaged position and a user presses the button 32, the dispensing member extends through the outlet 24,

7

thereby allowing the pill to be released to the user. In one embodiment, the button 32 communicates with the controller 18 to reset the timer 38 (as discussed below in further detail). Alternatively, the movement of the gate 16 from the engaged position A to the non-engaged position B automatically releases a pill at the outlet 24 of the container 12.

5

10

15

20

25

In one embodiment, the dispenser 10 includes a neutralizing device 22 in proximity to the contents of the chute 14 and the controller 18. As shown, the neutralizing device 22 may consist of a conduit that follows the outline of the chute 14. In this arrangement, the neutralizing device 22 may contain a material for rendering the pills located in the chute 14 impotent. For instance, the neutralizing device 22 may contain a flammable agent, such as model rocket fuel, that is ignited by an ignitor (not shown). Upon receipt of a signal from the controller 18 the ignitor may ignite the flammable agent for destruction of the contents of the dispenser 10. In addition to neutralization via a flammable agent, the neutralizing device 22 may contain a chemical that reacts with the active ingredients in the pill to render the pill physiologically inert.

In addition to the use of chemicals, the neutralizing device 22 may include an epoxy or other hard setting composition for physical encasement of the pills. This may include any quick-set epoxy or other adhesives or polymer known in the art. Additionally, the neutralizing device 22 may include a plunger (not shown) or other mechanical device for physical destruction of the pills.

Figure 5 shows a controller 18 for use with the dispenser 10. In one embodiment, the controller 18 includes at least one programmable microcontroller 34, such as the eight-pin microcontroller model number PIC12F675 manufactured by Microchip Technology, Inc., however, any

8

microcontroller 34 may be used. The microcontroller 34 may be programmed with the computer code attached in the Code Appendix, herein incorporated by reference. As shown, the microcontroller 34 receives power from a power supply 36, such as a battery or external power source. In one embodiment, the controller is powered by a standard 9-volt battery, however, any power source that provides the controller with the necessary power may be used.

5

10

15

20

25

The controller 18 also includes a timer 38 in communication with the microcontroller 34. The timer 38 works with the algorithm programmed in the microcontroller 34 to regulate the release of pills from the chute 14. In its most basic embodiment, the microcontroller 34 may include an algorithm for release of a pill from the chute 14 at a fixed interval of time. As illustrated in Figure 6a, this algorithm would permit the dispenser 10 to release a pill at fixed intervals of time, regardless of the time the user took the pill from the dispenser.

In another embodiment, the microcontroller 34 may include an algorithm for releasing pills at an adjusted fixed interval. As shown in Figure 6b, this algorithm would permit the dispenser 10 to release a pill at a fixed interval after the button 32 was pressed by the user and the pill was removed from the dispenser 10. In this embodiment, if the user was prescribed a pill release rate of 1 pill/4 hours, the dispenser 10 would release the pill 4 hours after the previous pill was removed from the dispenser 10. For instance, if the first pill was removed at 12:00, the next pill would be available at 4:00. However, if the user should forget to take the pill and waited until 5:00 to remove the pill from the dispenser 10, then the next pill would not be available until 9:00. Thus, the microcontroller 34 may include an algorithm for any pill release rate, whether fixed or variable. The microcontroller 34 may be programmed at the time of manufacture or it may be programmed by a drug

9

manufacturer, pharmacist, or other individual authorized to dispense the pills.

In addition to the microcontroller 34 working in conjunction with the timer 30 to release the pills, a sensor 20 is also in communication with the microcontroller 34. The sensor 20 detects tampering with the dispenser 10. If an individual should attempt to access the contents of the dispenser 10, the sensor 20 detects such activity, sends a signal to the microcontroller 34 and the microcontroller 34 activates the neutralizing device 22, thereby rendering the pills impotent.

5

10

15

20

25

In one embodiment shown in Figures 7a and 7b, the sensor 20 consists of a conductive loop 40 encasing the dispenser 10. As shown, the dispenser 10 is wrapped with a thin conductor 42. One end of the conductor 42 connects to ground G, the other connects to the microcontroller 34 and to the power supply 36. The microcontroller 34 is programmed to cause an interrupt on a change in the conductivity of the sensor 20. The conductor 42 is designed to break if the container 12 is broken or cut. When the conductor 42 is broken, the circuit opens and the microcontroller 34 detects an interrupt in the sensor 20. Upon detection of the interrupt in the conductor 42, the microcontroller 34 sends a signal to the neutralizing device 22 causing the neutralizing device 22 to destroy or render the contents of the dispenser impotent. In addition to the configuration of the wire conductor 42 wound around the container, the conductor may also take the form of a conductive pattern printed on paper, or as an etched pattern on a copper layer on the dispenser. Regardless of how the conductor 42 is implemented, the width of the conductor 42 and the spacing between conductors preferably would not exceed the width of a pill stored in the dispenser. Such a configuration would minimize the chances of an individual drilling a hole in the container or

10

otherwise accessing the contents of the container without breaking at least a portion of the conductor 42.

In another embodiment, shown in Figure 8, the sensor 20 includes a pressure sensitive switch 44 consisting of two layers of conductive material 45a, 45b separated by a small gap 46. If the dispenser 10 is crushed or cut, the two layers 45a, 45b will touch each other causing a short circuit. When the microcontroller detects a short circuit it actuates the neutralizing device.

5

10

15

20

25

In yet another embodiment, representatively shown in Figure 9, the sensor 20 comprises a capacitive sensor 47 made using a plurality of layers of conductive foil material separated by an insulator. The capacitance of the container depends on the spacing of the layers and the shape of the dispenser 10. Crushing, cutting, or other attack that changes the shape of the dispenser 10 will change its capacitance. The microcontroller 34 measures the capacitance, triggering the neutralizing device if the capacitance changes significantly. As shown in Figure 9, C<sub>container</sub> represents the capacitance of the container and C<sub>1</sub> is a known capacitance. The microcontroller 34 or power 'supply 36 repeatedly charges C<sub>container</sub> and distributes the charge between C<sub>1</sub> and  $C_{\text{container}}$ . The number of charge-discharge cycles required to make the voltage of  $C_1$  reach a certain threshold is proportional to the capacitance of  $C_{\text{container}}$ . The capacitive sensor 47 does not require a DC path between power and ground, but it does require the microcontroller 34 to be active to measure the capacitance of the container.

In another embodiment, shown in Figure 10, the dispenser 10 is pressurized and the sensor 20 comprises a pressure sensor 48, as known in the art. By comparing the internal pressure of the container with the external pressure outside the container, tampering can be detected. If the pressure

detected inside the dispenser 10 by the sensor 48 drops below a predetermined threshold value, the microprocessor 34 will activate the neutralizing device 22. Additionally, a change in the internal pressure of the dispenser 10 could also mechanically trigger a neutralizing device 22.

The present invention presents a pill dispenser 10 that dispenses pills no faster than a prescribed rate. Additionally, the dispenser detects tampering and, in the event of user tampering, renders the pills impotent.

5

10

20

25

The foregoing descriptions of various embodiments of the invention are provided for purposes of illustration, and are not intended to be exhaustive or limiting. Modifications or variations are also possible in light of the above teachings. For instance, in addition to the examples shown, the dispenser 10 may include any type of controller and/or sensor arrangement for detecting tampering. The dispenser 10 and its components may also form part of a kit including instructions on how to use it for controlling the rate of pill release and detect tampering. Additionally, the container and/or dispenser may be used for storing biological or organic hazards, such as anthrax. Upon detection of tampering with the container or dispenser the neutralizing device could destroy or render the biological or organic hazard inert. embodiments described above were chosen to provide the best application to thereby enable one of ordinary skill in the art to utilize the disclosed inventions in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally and equitably entitled.

. AIS PAGE BLANK (USPTO)